REMARKS

Applicant requests reconsideration of the present application in view of the foregoing amendments and the discussion that follows. The status of the claims is as follows. Claims 1-61 were originally filed. Claims 1 and 12 have been amended herein, Claims 62-63 were previously added and Claims 5-10, 14-20, 22-56, and 60-61 were previously canceled. Claims 5-7, 10, 16-20, 22-56, 60 and 61 were withdrawn from consideration in a previous Office Action and, thus, Applicant reserves the right to file divisional applications to the separately patentable subject matter of the aforementioned claims as well as to the non-elected species.

The Amendment

Claim 1 was amended to refer to a target molecule or target molecules. Support therefor is in the Specification, for example, the paragraph bridging pages 21-22.

Claim 1 was also amended to indicate that each of the electrodes comprises at least one target probe that binds to a target sequence to form a bimolecular complex. Support therefor is in the Specification, for example, Fig. 4 and page 23, line 7.

Claim 1 was amended to recite non-enzymatic ligand-bioconjugate pair. Support therefor is in the Specification, for example, page 27, lines 1-4 and 14-16. It should be noted that the Specification makes a clear distinction between ligand-bioconjugate pairs, on the one hand, and enzyme systems, on the other hand. It has been held that language for an amendment to a claim does not require literal support in an applicant's specification. See, for example, Ex parte Parks, 30 USPQ 2d 1234 (B.P.A.I. 1994). In the present situation, it is evident that Applicant made a clear distinction in the written description between ligand-bioconjugate pairs and enzyme systems, thus, adequately supporting the language "non-enzymatic ligand-bioconjugate pair."

Claim 12 was amended in a manner similar to that for Claim 1 above.

Previous rejections and objections

Applicant acknowledges the indication in the Office Action that Applicant's arguments, filed August 6, 2004, were fully considered and were deemed to be persuasive to overcome

the previous rejections of record. Applicant further acknowledges that rejections and/or objections not reiterated from previous office actions were withdrawn.

Applicant further acknowledges that the After Final amendment, filed August 6, 2004, was entered and that due to a newly found basis of rejection, the finality of the Office action, mailed June 3, 2004, was withdrawn.

Applicant would like to thank the Examiner for the telephone call of December 2, 2004, in which the Examiner indicated to the undersigned the aforementioned items. During the telephone call, no claim amendments were discussed, no exhibits were shown and no demonstrations were conducted.

Rejections under 35 U.S.C. §102

Claims 1-4, 11-13 and 21 were rejected under paragraph (e)(1) of the above code section as being anticipated by De Lumley-woodyear, *et al.* (U.S. Patent Application Publication 2002/0081588) (De Lumley-woodyear).

With respect to the above rejection, the Office Action characterized an enzyme as disclosed in the reference as one member of a bioconjugate pair, which the Office Action asserts is an option in instant claim 1. Without acquiescing in the above characterization, Applicant submits that Claim 1 now recites non-enzymatic ligand-conjugate pair. This language does not include the enzyme systems disclosed in the reference. In the present situation, therefore, De Lumley-woodyear does not disclose each and every element of the presently claimed invention of Claims 1 and 12 and those claims dependent therefrom. Accordingly, the above rejection cannot be maintained. *In re Paulsen*, 30 F.3d 1475, 1478, 31 U.S.P.Q.2d 1671, 1673 (Fed. Cir. 1994).

Rejections under 35 U.S.C. §103

Claims 1, 2, 4, 11-13, 21, 57-59, 62, and 63 were rejected under paragraph (a) of the above code section as being unpatentable over Blackburn, *et al.* (U.S. Patent No. 6,686,150) (Blackburn). The reference discloses compositions and methods useful in the detection of nucleic acids using a variety of amplification techniques, including both signal amplification and target amplification. Detection proceeds through the use of an electron transfer moiety (ETM) that is associated with the nucleic acid, either directly or indirectly, to allow electronic detection of the ETM using an electrode.

The Office Action contends that Blackburn discloses label probe/ETM hybridization to probe/target complex, which extends and incorporates the ETM thereby to result in

electrical detection via current flow via the electrode. The Office Action refers to column 4, lines 50-55, of Blackburn in support of this contention.

Step (b) of Claim 57 recites treating each test site, to which a target nucleic acid is hybridized, to extend the length of each oligonucleotide probe thereby incorporating an electronically responsive detector agent into each of the oligonucleotides where the electronically responsive detector agent is selected from the group consisting of transition metal complexes and non-enzymatic organic electron donors and acceptors. The oligonucleotide probes are attached to the test sites and target nucleic acids hybridize to respective attached probes. After the hybridization of the target nucleic acid(s) to the respective probes, the probes are treated to extend the probes and incorporate the electronically responsive detector agent.

The passage relied on by the Office Action in Blackburn must be read in context. Column 4, lines 45-50, of the reference, which immediately precedes the passage relied on, recites forming a first hybridization complex comprising an amplifier probe and a target sequence wherein the amplifier probe comprises at least two amplification sequences and wherein the first hybridization complex is covalently attached to an electrode comprising monolayers comprising conductive oligomers. The amplification does not incorporate an electronically responsive detector agent into a probe attached to the electrode as required in Claim 57. In the reference a probe, which is not attached to the electrode, is hybridized to a target and then amplified to form a complex, which is then attached to the electrode. No detector agent is incorporated in a probe attached to the electrode in a manner recited in Claim 57. This is clear from the language at the passage (column 4, lines 50-55) cited in the Office Action, which recites that at least one label probe comprising at least one electron transfer moiety (ETM) is hybridized to all or part of the at least one amplification sequence and then the labeled probe is detected. Accordingly, it is readily seen that the ETM moiety becomes bound to the first complex, which is subsequently covalently attached to the electrode. Again, there is no disclosure relevant to the method of Claim 57 wherein a detector agent is incorporated into a probe attached to the test site after a target nucleic acid is hybridized to the probe.

All of the amplifications employed by Blackburn appear to be conducted prior to hybridizing a moiety to the electrode. There is no disclosure in Blackburn of the extension of the type set forth in Claim 57 to incorporate a detector agent into a

probe, which is attached to a test site and to which is first hybridized a target nucleic acid.

Claims 1 and 12, and those claims depending therefrom, are not disclosed or suggested by Blackburn. Claims 1 and 12 recite that each of the electrodes comprises at least one target probe that binds to a target molecule to form a bimolecular complex. As can be seen, for example, from the figures of Blackburn and accompanying disclosure, the concept involved in the reference is to employ multiple probes per target molecule or to incorporate multiple ETM's into a target molecule, which is then hybridized to an electrode. The present Claims 1 and 12 are directed to methods involving one probe per one target sequence where the probe is attached to a test site and where the probe comprises an electronically responsive detector agent.

Conclusion

Claims 1-4, 11-13, 21, 57-59 and 62-63 satisfy the requirements of 35 U.S.C. §§102 and 103. Allowance of the above-identified patent application, it is submitted, is in order.

Respectfully submitted,

Theodore J. Leitereg
Attorney for Applicant
Reg. No. 28,319

Agilent Technologies, Inc.
Legal Department, M/S DL429
Intellectual Property Administration
P.O. Box 7599
Loveland, CO 80537-0599